

Claims 1-10 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-10 and 12-19 of U.S. Patent Application No. 09/716,022 (hereafter the '022 application).

Applicants have reviewed the claims of the *pending* application, also identified as attorney docket number 273012011500, and note that this rejection appears to be *provisional* in nature because the claims of the '022 application have not yet been patented.

Because the rejection is *provisional* in nature and in light of the traversal below, Applicants believe that no Terminal Disclaimer is appropriate at this time.

Contrary to the statement of the rejection, the claims of the instant application differ from those of the '022 application in patentably distinct ways beyond those cited by the Examiner. For example, the instant claims are directed to the use of low dose photodynamic therapy (PDT) in adjunct with an angioplasty procedure while the claims of the '022 application are directed to the use of PDT in cases of a vein, artery, or vascular graft. Angioplasty does not require the use of a graft; similarly, vascular grafts need not be practiced with angioplasty.

To establish a *prima facie* case, an assertion of obviousness-type double patenting requires the application of the same standards as an allegation of unpatentability due to obviousness (see MPEP 804II.B.1.). Applicants respectfully submit that no *prima facie* case of obviousness-type double patenting has been presented because no suggestion or motivation has been provided to make the changes necessary to go from the methods of treating grafts as claimed in the '022 application to the methods of treating restenosis or intimal hyperplasia in adjunct with angioplasty as encompassed by the instant claims.

Applicants respectfully submit that the claims of the '022 application and the instant case are directed to applications of photodynamic therapy (PDT) in different fields relating to the practice of vascular grafts and angioplasty, which are patentably distinct. Accordingly this *provisional* rejection is misplaced and may be properly withdrawn.

Rejection under 35 U.S.C. § 112

Claims 1-10 has been rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for use of the term "prevent". Applicants have carefully reviewed the statement of the rejection and believe that the claims are definite for the following reasons.

The statement of the rejection alleges that the metes and bounds of the invention are not clearly set forth. Moreover, the statement of the rejection appears to require information of “how and when to prevent restenosis or intimal hyperplasia” as well as “the degree of prevention”.

As an initial matter, Applicants point out that the claims are not directed to preventing restenosis or intimal hyperplasia (IH) as an abstract concept. Instead, the claims are directed to such prevention “in adjunct with angioplasty”.

Therefore, claim 1 has not been amended based upon the Memorandum dated January 17, 2003 from Stephen Kunin, Deputy Commissioner for Patent Examination Policy at the U.S. PTO (copy attached). The Memorandum sets forth a clarification and immediate implementation of policy with respect to rejections under 35 U.S.C. § 112, second paragraph. Of particular relevance to the instant rejection is the statement that

“[I]f the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim *so as to understand how to avoid infringement*, a rejection of the claim under 35 U.S.C. § 112, second paragraph would be appropriate.” (*emphasis added*)

Applicants believe that this means that if an artisan of ordinary skill can interpret the metes and bounds of the claim *to avoid infringement*, no rejection under 35 U.S.C. § 112, second paragraph is proper.

Additionally, Applicants point out the emphasis in the Memorandum on considering “the claim as a whole” as opposed to a focus on particular words or phrases in a claim. This is discussed further on page 2, first full paragraph, of the Memorandum which includes an example concerning the use of the phrase “such as” in a claim. This example is used to modify previous practice as set forth at MPEP 2173.05(d).

Based upon the Memorandum, Applicants respectfully submit that a skilled person would understand the scope of the claimed invention sufficiently to avoid infringement. Claim 1 specifically recites administration of the photosensitizer used “to a blood vessel that has undergone angioplasty”. Only prevention of restenosis or IH *after angioplasty* is encompassed by the claims. This alone should rendered 35 U.S.C. § 112, second paragraph satisfied for the reasons provided in the Memorandum because an ordinary artisan would recognize that the

claims are directed to a prevention period after angioplasty and before the onset of restenosis or IH. Once onset has begun, any practice of the claimed invention would be to “treat, inhibit, or reduce” restenosis or IH rather than prevent it. Moreover, and with respect to the question of “how” as raised in statement of the rejection, the ordinary artisan would recognize that the “how” of prevention as claimed is clearly via use of the method as claimed. Therefore, the ordinary artisan can readily determine how to avoid infringement when practicing low dose PDT in adjunct with angioplasty.

With respect to the alleged ambiguity as to the “degree of prevention”, Applicants respectfully submit that the broadest interpretation of “prevent” as used in the claims encompasses all the “degrees of prevention” suggested in the statement of the rejection. Simply put, the term is broad, but breadth does not equal indefiniteness (see MPEP 2173.04 and the case cited therein). The term “infinity” for example, is extremely broad, but not indefinite. Similarly, the scope of preventing restenosis or intimal hyperplasia to any degree, while broad, is not indefinite.

In light of the above, Applicants respectfully submit that the claims are definite and request withdrawal of the instant rejection.

Prior art rejection under 35 U.S.C. § 103

Claims 1-10 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Vincent (USP 5,422,362) and Vincent et al. (“Effects of benzoporphyrin derivative monoacid on balloon injured arteries in a swine model of restenosis,” in Lasers in Surgery: Advanced Characterization, Therapeutics, and Systems VI, R.Rox Anderson, M.D., Ed. Proc. SPIE 2671, 72-77 (1996)). Applicants have carefully reviewed the statement of the rejection as well as the cited references and respectfully traverse as follows.

As an initial matter, the rejection appears to be based upon various misunderstandings of what the references disclose. In the interest of clarity in the record, Applicants begin by pointing out each misunderstanding found in the statement of the rejection. The Examiner is invited to comment with particularity on the following in the interest of the clearest possible record.

As an initial matter, Vincent (‘362) discloses the use of a green porphyrin “in the absence of purposeful irradiation with light” (see column 3, lines 45-52) in conjunction with angioplasty.

This is in contrast to the instant claims, directed to the use of purposeful irradiation of a photosensitizer as part of photodynamic therapy (PDT).

Applicants believe that the following statement, from page 5, first complete sentence, of the Office Action mailed November 5, 2002, is in error:

“Vincent’362 also teaches the presence of smooth muscle cells after the BPD-MA therapy, i.e., without depleting all cells at the site (See particularly col. 11, line 16-19)” (underlining in original).

Applicants point out that the observation of smooth muscle cells (SMCs) was made in the vasculature of rabbits administered BPD-MA *without irradiation* (see column 10, lines 46-56). Moreover, the observation was made in rabbits sacrificed after four months, which is at least one month following the last administration of BPD-MA (see column 10, lines 54-60). It is simply unknown whether the observed SMCs are those present despite the BPD-MA administration or new cells that have repopulated an acellular area after the BPD-MA administration. Therefore, and contrary to the statement, it is unknown whether cells were depleted at the site of injury during PDT.

Applicants also believe that the following statements, from page 5, second complete sentence, of the Office Action mailed November 5, 2002, is in error:

“Vincent’362 also teaches the use of Photofrin II, also known as porfimer sodium, in the concentration of 2µg/ml, *to treat restenosis* with light energy of greater than 3 J/cm². Such treatment results in the destruction of over 80% of smooth muscle cells (See col. 2, line 40-57).” (*emphasis added*)

Applicants respectfully submit that the passage in column 2, lines 40-57, of Vincent (‘362) describe the work of Sobeh et al. with smooth muscle cells “cultured from the intermedia” of a human long saphenous vein. As the Examiner will no doubt appreciate, the treatment of cells in culture is **not the same as treating restenosis** in a blood vessel that has undergone angioplasty.

In light of the above discussion, it is not clear to Applicants how Vincent (‘362) is even relevant to the instant claims. Assuming *in arguendo* that the reference may be characterized as generally directed to the use of a photosensitizer in connection with angioplasty, the particulars

of the treatment are very different from those of the claimed invention. Most notably is the absence of purposeful irradiation by Vincent ('362) in contrast to the express inclusion of purposeful irradiation in the instant claims.

As for the teachings of Vincent et al. (1996), Applicants believe the following statement on page 6, first sentence, of the Office Action mailed November 5, 2002 is in error:

“Based on the teachings of Vincent et al., 30 J/cm² is known to be effective in treating restenosis and not totally destruct smooth muscle cells.”

To the contrary, Vincent et al. (1996) expressly teach that their use of photodynamic therapy (PDT) with laser light and BPD “increased intimal hyperplasia” (see page 76, first sentence of second full paragraph). Only one group (“Group 4”) of Vincent et al. (1996)’s treatment of injured blood vessels in a porcine model of restenosis was actually treated with PDT, and the group was found to have increased intimal hyperplasia as reflected in the data in Table 2, page 75 of the reference. How does the observation of increased intimal hyperplasia render the instant claims, directed to decreasing intimal hyperplasia, obvious? Moreover, the disclosure of cells as not totally eradicated is based on animals sacrificed six weeks after the start of the experiment. As noted above with respect to Vincent ('362), this provides no information concerning the depletion of cells at the site of injury during PDT.

A more extensive review of Vincent et al. (1996) reveals that they suggest that the use of laser light results in intimal proliferation (page 76, second full paragraph) and that the “dark effect” of BPD *without irradiation* is a potential treatment of restenosis (page 76, third full paragraph).

In light of the above discussion, Applicants respectfully submit that no *prima facie* case of obviousness has been presented. The cited references clearly do not teach all the limitations of the claims, which include the use of purposeful irradiation, of about 0.25 to about 25 J/cm², to **decrease** restenosis or intimal hyperplasia. Instead, Vincent et al. (1996) teach the *opposite* result of increasing intimal hyperplasia.

Additionally, and contrary to the instantly claimed methods, both references point squarely at omitting the use of purposeful irradiation. Vincent ('362) expressly teach this, and Vincent et al. (1996) suggest this based upon their observations. Based upon this, Applicants

submit that no motivation to combine these references to arrive at the claimed invention can be found in the references or knowledge in the art.

Moreover, and contrary to the allegation in the statement of the rejection, no motivation based upon an "obvious to optimize" standard is present. Vincent et al. (1996) actually suggests that irradiation causes intimal proliferation, and so optimization of irradiation would only serve to continue to cause increases in intimal hyperplasia. Additionally, the combination of the two references actually teaches away from the use of irradiation and toward the omission of purposeful irradiation to activate a photosensitizer.

In light of the above, Applicants respectfully submit that no *prima facie* case of obviousness has been presented and that this rejection should be withdrawn.

CONCLUSION


In light of the above discussion and traversals, Applicants believe that the claims are in condition for allowance and urge early indication to that effect. The Examiner is encouraged to contact the undersigned to expedite prosecution of the instant application.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 273012012200.

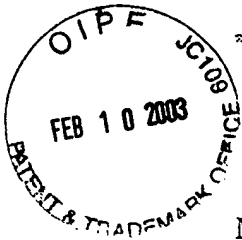
Respectfully submitted,

Dated: February 4, 2003

By: _____


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Commissioner for Patents
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Memorandum

Date: January 17, 2003

To: Technology Center Directors
Patent Examining Corps

From: 
Stephen G. Kunin
Deputy Commissioner for Patent Examination Policy

Subject: Advance notice of changes to MPEP § 2173.02 clarifying Office policy with respect to rejections made under 35 U.S.C. § 112, second paragraph in view of the Supreme Court holding in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S.Ct. 1831, 62 USPQ2d 1705 (2002)

This memorandum clarifies Office policy with respect to rejections made under 35 U.S.C. § 112, second paragraph. The guidance provided herein is effective immediately and should be applied by all Office personnel. These changes will be published in the next revision of the MPEP.

As noted in MPEP § 2173.02, during examination of claims for compliance with the requirements for definiteness under 35 U.S.C. § 112, second paragraph, some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. In reviewing a claim for compliance with 35 U.S.C. § 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. § 112, second paragraph by providing clear warning to others as to what constitutes infringement of the patent. See *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. § 112, second paragraph would be appropriate. See *Morton Int'l, Inc. v. Cardinal Chemical Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993). However, if other modes of expression selected by applicants satisfy the statutory requirements of 35 U.S.C. § 112, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used, the claim must not be rejected under 35 U.S.C. § 112,

second paragraph, rather, the examiner should suggest improved language to the applicant.

For example, a claim recites “a suitable liquid such as the filtrate of the contaminated liquid to be filtered and solids of a filtering agent such as perlite, cellulose powder, etc.” The mere use of the phrase “such as” in the claim does not by itself render the claim indefinite. Office policy is not to employ *per se* rules to make technical rejections. Examples of claim language which have been held to be indefinite set forth in MPEP § 2173.05(d) are fact specific and should not be applied as a *per se* rule. The test for definiteness under 35 U.S.C. § 112, second paragraph is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). If one skilled in the art is able to ascertain in the example above, the meaning of the terms “suitable liquid” and “solids of a filtering agent” in light of the specification, 35 U.S.C. § 112, second paragraph is satisfied.

If upon review of the claim as a whole in light of the specification, the examiner determines that a rejection under 35 U.S.C. § 112, second paragraph is not appropriate in the above-noted example, but is of the opinion that the clarity and the precision of the language can be improved by the deletion of the phrase “such as” in the claim, the examiner may make such a suggestion to the applicant. If applicant does not accept the examiner’s suggestion, the examiner should not pursue the issue.

If upon review of a claim in its entirety, the examiner concludes that a rejection under 35 U.S.C. § 112, second paragraph is appropriate, such a rejection should be made and an analysis as to why the phrase(s) used in the claim is “vague and indefinite” should be included in the Office action. If applicants traverse the rejection, with or without the submission of an amendment, and the examiner considers applicants’ arguments to be persuasive, the examiner should indicate in the next Office communication that the previous rejection under 35 U.S.C. § 112, second paragraph has been withdrawn and provide an explanation as to what prompted the change in the examiner’s position (e.g., examiners may make specific reference to portions of applicants’ remarks that were considered to be the basis as to why the previous rejection was withdrawn).

By providing an explanation as to the action taken, the examiner will enhance the clarity of the prosecution history record. As noted by the Supreme Court in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S.Ct. 1831, 1838, 62 USPQ2d 1705, 1710 (2002), a clear and complete prosecution file record is important in that “[p]rosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process.” In *Festo*, the court held that “a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel.” With respect to amendments made to comply with the requirements of 35 U.S.C. § 112, the court stated that “[i]f a § 112 amendment is truly cosmetic, then it would not narrow the patent’s scope or raise an estoppel. On the other hand, if a § 112 amendment is necessary and narrows the patent’s scope—even if only for the purpose of better description—estoppel may apply.” *Id.*, at 1840, 62 USPQ2d at 1712. The court further stated that “when the court is unable to determine the purpose underlying a narrowing amendment—and hence a rationale for limiting the estoppel to the surrender of particular equivalents—the court should presume that the patentee surrendered all subject

matter between the broader and the narrower language...the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question." *Id.*, at 1842, 62 USPQ2d at 1713. Thus, whenever possible, the examiner should make the record clear by providing explicit reasoning for making or withdrawing any rejection related to 35 U.S.C. § 112, second paragraph.